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THE UNITED STATES PATENT

AND TRADEMARK OFFICE

AUG 16 2007

rial No. : 10/535,000

Applicants : Masakazu HATANO et al.

Filed : May 16, 2005

For : THERAPEUTIC AGENT FOR

GLAUCOMA COMPRISING Rho

KINASE INHIBITOR AND

β-BLOCKER

Art Unit : 1618

Examiner : Zohreh FAY

Docket No. : 05318/HG

Confirm No.: 1933

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Date of Deposit: August 16, 2007 I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 with sufficient postage on the date indicated above and is

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MAIL STOP AMENDMENT
Commissioner for Patents.
P.O. Box 1450
Alexandria, VA 22313-1450

Anester De Frencaser

Dorothy DeFrancesco

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by Form PTO-2038 attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

MAIL STOP AMENDMENT

SIR:

Submitted concomitantly herewith are the following:

- (1) A copy of a Supplementary Partial European Search
 Report, which issued in the counterpart European application;
- (2) IDS Forms. It is respectfully requested that initialed copies of the enclosed IDS Forms be returned to the undersigned to indicate that the publications listed therein have been considered and made of record; and

(3) Copies of the non-U.S. patent documents cited in said IDS Forms.

Each of the cited publications in the enclosed Search Report is considered relevant or material to the patentability of the present claims in view of the citation thereof in said Search Report.

Said Search Report is in English, thereby satisfying the requirements for a concise explanation of relevance for the publications cited therein.

The following publication, which was cited in the enclosed Supplementary Partial European Search Report, was cited in the INFORMATION DISCLOSURE STATEMENT dated June 27, 2005:

HONJO MEGUMI et al., "Effects of Rho-associated protein kinase inhibitor Y-27632 on intraocular pressure and outflow facility," <u>Investigative Ophthalmology & Visual Science</u>, <u>Association for Research in Vision</u>, Vol. 42, No. 1, January 2001, pp. 137-144.

The following is a copending related application: Serial No. 10/525,986 (published as US 2005/0245509).

The enclosed IDS Forms include publications cited in application Serial No. 10/525,986.

Further submitted herewith is a corrected Sheet 2 of 2 of Form PTO/SB/08B dated June 27, 2005, which serves to correct a typographical error in the author's name of the first cited publication, namely "UEHARA, M. et al." was replaced with --UEHATA, M. et al.--.

Please substitute the enclosed Sheet 2 of 2 of Form
PTO/SB/08B dated June 27, 2005 for the Sheet 2 of 2 of Form
PTO/SB/08B filed on June 27, 2005.

Respectfully submitted,

RICHARD S. BARTH REG. NO. 28,180

FRISHAUF, HOLTZ, GOODMAN & CHICK, P.C. 220 FIFTH AVENUE, 16th FLOOR NEW YORK, NEW YORK 10001-7708 Tel. Nos. (212) 319-4900 (212) 319-4551/Ext. 219

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RSB/ddf

Encs.: (1) copy of Supplementary Partial European Search Report dated June 4, 2007

- (2) IDS Forms
- (3) copies of non-U.S. documents cited on the enclosed IDS Forms

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489 TODY						Application Number			10/535,000			
		\ \tag{3}	AUG 16	2007	Fi	ling	Date	Ma	May 16, 2005			
INFOR			CLOS	UREO .	Fi	rst N	amed Inventor	Masakazu HATANO				
					Gr	Group Art Unit			1618			
					Ex	Examiner Name			Zohreh FAY			
Sheet 1 of 2					At	Attorney Docket Number			5318/HG			
	<u> </u>		· · ·	บ	.s.	PATE	ENT DOCUMENTS					
Exam. Inits*	Cite No¹	e Document Number			-	Kind Code ²	Name of Patentee of Applicant	or	Publication Date MM-DD-YYYY	Relevan Portion		
		2005/0245509 4,952,581				A1	NAKAJIMA et al.		11-03-2005			
							BITO et al.		08-28-1990			
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Exam Inits	Cite No¹	Offc³	Documer	nt Number4		Kind Code⁵	Name of Patentee of Applicant	or —	Publication Date MM-DD-YYYY	Relevant Portion	T ⁶	
/G.H./		WO	00/579	14		A1	SANTEN PHARMACEUTICAL CO)	10-05-2000		a	
/G.H./		WO	00/257	71		A1	SYNPHORA AB		05-11-2000			
/G.H./		wo	90/025	53		A1	PHARMACIA AB		03-22-1990			
/G.H./		EP	308135			A2	K. K. UENO SEIYAI	KU	03-22-1989			
/G.H./		WO	94/064	33		A1	ALLERGAN INC		03-31-1994			
/G.H./		EP	639563			A2	ALCON LAB INC		02-22-1995			
/G.H./		WO	00/091	.62		A1	SENJU		02-24-2000		a	

* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Considered

02-19-1998

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YOSHITOMI

Date

DATE: <u>August 16, 2007</u>

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98/06433

/Gigi Huang/

abstract only

/G.H./

Examiner

Signature

¹ Unique citation designation number. ² See kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Place a check here if English translation is attached.

a ENGLISH-LANGUAGE ABSTRACT ENCLOSED

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

The Hot	ow.				Applicati	on Number	10/535,000	10/535,000		
IDS FORM INFORMATION DISCLOSURE STATEMENT BY APPLICANT					Filing Da	ite	May 16, 2005			
					First Named Inventor Masakazu HATANO					
		•			Group Art	Unit	1618			
					Examiner	Name	Zohreh FAY	-		
Sheet	eet ² of ²		2	Attorney	orney Docket Number 05318/HG					
		ОТНЕ	ER D	OCUMENTS	- NON-PA	TENT LITERAT	URE DOCUMENTS			
Examiner Initials ¹	Cite No.1									
/G.H./		ABATE M.A. et al., "Effect of Naproxen and Sulindac on Blood Pressure Response to Atenolol," DICP - ANNALS. OF PHARMACOTHERAPY, Vol. 24, no. 9, 1990, pp, 810-813								
/G.H./		ZHOU YAN et al., "Nonsteroidal Anti-Inflammatory Drugs Can Lower Amyloidogenic $A\beta_{42}$ by Inhibiting Rho," Science, Vol. 302, no. 5648, 14 November 2003, pp. 1215-1217								
/G.H./		HONJO et al., "Effects of Protein Kinase Inhibitor, HA1077, on Intraocular Pressure and Outflow Facility in Rabbit Eyes," <u>Archives of Ophthalmology</u> , Vol. 119, no. 8, August 2001, pp. 1171-1178								
/G.H./		DATABASE WPI Week 200060, Derwent Publications ltd., London, GB; AN 2000-628321 of WO 00/57914 (Santen Pharmaceutical Co., Ltd.; Oct. 5, 2002)								
/G.H./		CLARK A.F. et al., "Advances in Glaucoma Therapeutics," Expert Opinion of Emerging Drugs, 2002, United Kingdom, Vol. 7, no. 1, May 2002, pp. 141-163								
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Examiner Signatur		/Gigi Huang/				Date Considered	11/20/2008			

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DATE: <u>August 16, 2007</u>

¹ Unique citation designation number. 2 Place a check here if English translation is attached.

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Substitute fo	or Form 144	9A/PTO	Application	on Number	10/535,000					
			Filing Dat	e	MAY 16, 2005					
INFORMATION STATEMENT E			First Name	ed Inventor	Masakazu HATANO					
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			Examiner N	Vame	Zohreh FAY					
Sheet	2 of 2		Attorney I	Docket Number	05318/HG					
	OTHER D	OCUMENTS	- NON-PAT	ENT LITERAT	URE DOCUMENTS					
Examiner Cite Initials No. 1	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published T ²									
/G.H./ UEHATA, M. et al., "Calcium Sensitization of Smooth Muscle Mediated by a Rho-Associated Protein Kinase in Hypertension," Nature, (1997), 389, pp. 990 to 994.										
	Maniha 2024	r3			Vielenza (Delenzala Obida Manual					
hot consider	II. Dai 10				Yakuzai (Bukuyaki Shido Manual 38(9), pp. 2311 to 2331.	0000000000				
	1	•		-	Gairen (Chirpeyaku no Sentaku Therapy") Ganka. (2002).	000000000				
o Dou Kangaerunoka),"("Some Practical Aspect in Medical Therapy") Ganka, (2002), 44(11), pp. 1443 to 1448. not considered										
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not conside	pp. 1458 to	1463.	anyana, (p m	aremergre .m.eugom	ges , danka, (2002), <u>11121,</u> ,					
/G.H./	/G.H./ Ikuo AZUMA et al., "Effects of Bunazosin Hydrochloride Ophthalmic Solution in Combination with Timolol Maleate Ophthalmic Solution in Patients with Open-Angle									
abstract onl	Glaucoma and Ocular Hypertension-Comparison with Dipivefrin Hydrochloride Ophthalmic Solution, The Journal of the Eye, (2002), 19(2), pp. 261 to 266. Ohtake									
/G.H./	Yuichiro **** at al., "Effect and Safety of Combined Therapy with Betaxolol and isopropyl Unoprostone," The Journal of the Eye, (2000), 17(5), pp. 687 to 690.									
abstract or	ly	,		· · · · · · · · · · · · · · · · · · ·	<u> </u>					
	Hideki TOKUSHIGE, "ROCK Sogaiyaku to Ryokunaisho" ("ROCK Inhibitor and Glaucoma"), BIO Clinica, (2002), 17(13), pp. 1191 to 1194.									
/G.H./	HOYNG, P.F.J. et al., "Pharmacological Therapy for Glaucoma," <u>Drugs</u> , (2000), <u>59(3)</u> , pp. 411 to 434.									
/G.H./	Megumi HONJO et al., "Effects of Rho-Associated Protein Kinase Inhibitor Y-27632 on Intraocular Pressure and Outflow Facility," <u>Invest. Ophthalmol. & Vis. Sci.</u> , Vol. 42, No. 1 (2001). pp. 137-144.									
/G.H./	P. Vasantha RAO et al., "Modulation of Aqueous Humor Outflow Facility by the Rho Kinase-Specific Inhibitor Y-27632," <u>Invest. Ophthalmol. & Vis. Sci.</u> , Vol. 42, No. 5 (2001), pp. 1029-1037.									
Examiner Signature	/Gigi H	uang/		Date Considered	11/20/2008					

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